

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

In Re: Valsartan, Losartan, and Irbesartan
Products Liability Litigation

Case No. 19-md-02875 (RBK/KW)

This Document Relates to All Actions

**LOSARTAN AND IRBESARTAN PLAINTIFFS' REQUESTS FOR
PRODUCTION OF DOCUMENTS TO WHOLESALER
DEFENDANTS**

TO ALL WHOLESALER DEFENDANTS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 34 and Local Civil Rule 34.1, Plaintiffs propound the following requests upon each Wholesaler Defendant.¹ These requests are without prejudice to Plaintiffs' rights to serve other requests consistent with Rules 26 and 34.

The Wholesaler Defendants have previously advised, and Plaintiffs understand, that there may be differences in the type and extent of data available and the type and extent of data available in a reasonably accessible format. Following service of these requests for production, each Wholesaler Defendant shall serve its own individual responses to the requests set forth below, specifying any issues that the Wholesaler Defendant has with responding to the requests. The Parties will meet and confer in good faith on the substance of any such responses, including to the extent necessary to address Plaintiffs' reasonable questions regarding Wholesaler Defendant's answers.

¹ To the extent it applies, these requests are made in accordance with the Court's prior rulings, including discovery issues following argument of the Parties on July 6, 2020, (D.E. 507).

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DEFINITIONS

“Active Pharmaceutical Ingredient” (“API”) is defined as any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance. 21 C.F.R. § 207.1; see also 21 C.F.R. § 314.3.

“API Manufacturer” is defined as any entity identified as a Defendant in Plaintiffs’ Master Complaints that manufactures the active pharmaceutical ingredient (API) for losartan or irbesartan.

“Finished Dose Manufacturer” includes any entity identified as a Defendant in Plaintiffs’ Master Complaints that manufactures valsartan in a finished dosage form that is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of losartan or irbesartan. The term “finished dose manufacturer” also includes entities who hold ANDAs.

“Manufacturer Defendants” includes API Manufacturers and Finished Dose Manufacturers including any subsidiaries or affiliated entities.

“Communication(s)” means the transmittal of information, in the form of facts, ideas, inquiries, documents or otherwise, and includes all transmissions of information received or transmitted by you, including correspondence, regardless of whether you are an author or addressee of such transmittal.

“Documents” includes, without limitations, any written, printed, typed, photostatic, photographic, recorded or otherwise reproduced or reproducible communication or representation (including attachments to mails), whether comprised of letters, words, numbers, pictures, sound or symbols, or any combination thereof, whether intended for internal use, dissemination to outside entities, or any combination thereof.

This definition includes copies or duplicates of documents contemporaneously or subsequently created that have any nonconforming notes or other markings. Without limiting the generality of the foregoing, the term “Document” includes, but is not limited to, correspondence, memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, working papers, summaries, statistical statements, financial statements, presentations, work papers, accounts, invoices, purchase orders, ledgers, journals, book of accounts, local records, reports and/ or summaries of investigation, trade letters, press releases, comparisons, books, calendars, calendar entries or invitations, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, drawings, diagrams, instructions, notes or minutes of meeting, or other communications of any type, including inter-office and intra office communication, questionnaires, surveys, charts, graph, photographs, recordings, tapes, back-up tapes, discs, data cells, printouts, all other data compilations from which information can be obtained (translated, if necessary, into usable form). Such reference to documents includes originals and copies, microfilms and transcripts made, recorded, produced or reproduced by any and every means. “Documents” also includes the content of any applicable computer database. For purposes of these discovery requests, “Documents” shall refer only to centrally stored,

noncustodial data maintained by the retailer pharmacy in the ordinary course of business and available via reasonable search of available records and in a reasonably accessible format, and shall not refer to documents or data maintained solely by individual stores or pharmacies, or to emails or custodial data held by individual employees of the Retail Pharmacy Defendants.

Relevant Time Period: Unless otherwise specified, the relevant time period applicable to all requests is January 1, 2011 through December 31, 2019. (If a Defendant is aware that the time period should extend beyond December 31, 2019 please confirm the appropriate date and basis therefor).

“Retail Pharmacy Defendants” refers to any and all entities listed by name as “Retail Pharmacy Defendants” in Plaintiffs’ Master Complaints, including any agents or predecessor entities.

“TPP” refers to Third Party Payors, including health insurance companies, third-party administrators, health maintenance organizations, self-funded health and welfare benefit plans, third party payors, and any other health benefit provider in the United States of America and its territories.

“Losartan” or “LCDs” means any drug with losartan as an active ingredient. For purposes of these Requests, “Losartan” or “LCDs” is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs’ Master Complaints.

“Irbesartan” or “ICDs” means any drug with irbesartan as an active ingredient. For purposes of these Requests, “Irbesartan” or “ICDs” is limited to only those drugs with a National Drug Code (NDC) associated with any of the Manufacturer Defendants identified in Plaintiffs’ Master Complaints.

“Recalled Product” means any drug with losartan or irbesartan as an active ingredient, as well as all finished drug formulations of losartan or irbesartan, including any losartan-containing drug or irbesartan-containing drug, that was subject to a voluntary or mandatory recall, to the extent identifiable from Documents kept by the Retail Pharmacy Defendant(s) in the ordinary course of business.

“You,” “your” or “defendant” shall be used interchangeably and refers to the parties to which these requests are directed.

“Drug Supply Chain Security Act” refers to Pub. L. 113-54 and regulations promulgated thereunder.

“Wholesaler Defendants” refers to Amerisource Bergen Corporation, Cardinal Health, Inc., or McKesson Corporation, as identified in Plaintiffs’ Master Complaints, including any agents, employees, or predecessor entities, to the extent known to the Retail Pharmacy Defendants.

INSTRUCTIONS

Non-privileged information: These Requests seek only information that is not privileged or otherwise protected from disclosure by applicable protection, including but not limited to work product protection or other requirements imposed or protections afforded by applicable law or regulation. This does not relieve any responding Defendant from serving a privilege log consistent with the Federal Rules of Civil Procedure.

DOCUMENTS TO BE PRODUCED

I. SOURCING (UPSTREAM)

1. For purchases of LCDs and ICDs by you from Manufacturer Defendants during the time period from January 1, 2011 to December 31, 2019, produce documents identifying the dates of purchase, the quantities/units purchased, the NDC, batch and lot numbers, and expiration date (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search) for the LCDs and ICDs purchased, and the name of Manufacturer Defendant from whom the LCDs and ICDs were purchased.
2. Produce a sworn response in the following table:

Date of Purchase	NDC Code	Lot or Batch Number	Expiration Date	Finished Dose Manufacturer	API Manufacturer	Entity Product was Purchased From	Price Per Pill	Pill Quantity Purchased	Number of Pills Subject to Recall	Number of Pulls Recovered in Any Recall	State Where Wills Were Dispensed

II. SALES (DOWNSTREAM)

2. For sales of LCDs and ICDs by you to Retail Pharmacy Defendants during the time period from January 1, 2011 to December 30, 2019, documents identifying the quantities/units sold, the NDC, batch and lot numbers, and expiration date (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search), and purchaser name.
3. Produce a sworn response with the following information:

Date of Sale	NDC Code	Lot or Batch Number	Expiration Date	Finished Dose Manufacturer	API Manufacturer	Entity Product was Purchased From	Price Per Pill	Pill Quantity Sold	Number of Pills Subject to Recall	Number of Pulls Recovered in Any Recall	State Where Wills Were Dispensed

III. WARRANTIES/STATEMENTS (UPSTREAM)

4. Produce documents sufficient to identify your final written policies, if any, that set forth the shipment and other documents you require be provided to you by a Manufacturer Defendant.
5. Produce exemplar documents sufficient to identify the type of manufacturer-included packaging or labeling documents, shipment documents, and similar information which accompany LCDs and ICDs sold to you by the Manufacturer Defendants.

IV. WARRANTIES/STATEMENTS (DOWNSTREAM)

6. Produce documents sufficient to identify your final written policies, if any, that set forth the shipment and other documents you require be provided by you to Retail Pharmacy Defendant(s) or other retail pharmacies concerning LCDs or ICDs sold by you.
7. Produce documents sufficient to identify as exemplar the manufacturer-included packaging and labeling documents, shipment documents, and similar information which accompany LCDs and ICDs sold by you to Retail Pharmacy Defendants and other retail pharmacies.

V. TESTING/INSPECTION

8. Produce documents sufficient to identify the testing and testing results of LCDs or ICDs provided to you by the Manufacturer Defendants for LCDs or ICDs purchased by you during the time period from January 1, 2011 to December 30, 2019, or otherwise known to you or available to you.
9. Produce documents sufficient to identify the testing, if any, you performed on LCDs and ICDs purchased by you from Manufacturer Defendants, or otherwise available to you, and results thereof, during the time period from January 1, 2011 to December 30, 2019.

VI. DISTRIBUTION CENTERS

10. Produce documents sufficient to identify your distribution centers from which LCDs and ICDs purchased by you from Manufacturer Defendants were shipped, including location and state(s) served by each distribution center.
11. To the extent available, produce documents sufficient to identify your distribution centers that received or shipped LCDs and ICDs purchased by you from Manufacturer Defendants subject to recall.

VII. RECALL

12. Produce documents sufficient to identify your final written policies and procedures specifically governing the LCD and ICD recalls, if any.
13. Produce documents sufficient to show the initial LCD and ICD recall communications you received from the Manufacturer Defendants from whom you purchased LCDs and ICDs.

14. Produce documents sufficient to show the official notice, if any, by which you communicated any LCD and ICD recall to any Retailer Defendant.
15. Produce documents sufficient to identify by NDC, batch and lot numbers (to the extent such information is maintained by you in the ordinary course of business and can be obtained following a reasonable search) recalled LCDs and ICDs: (a) currently on hand; (b) returned by you; or (c) destroyed by you.
16. Produce documents sufficient to identify a list of your significant employees involved in managing the recall of LCDs and ICDs.
17. Produce documents sufficient to identify distribution facilities that received any recalled LCD or ICD.

VIII. COMPLIANCE WITH THE DRUG SUPPLY CHAIN SECURITY ACT

18. Documents sufficient to identify your final written policy(ies) and procedures used by you to track purchases and sales of prescription drugs pursuant to the Drug Supply Chain Security Act and regulations promulgated thereunder and/or final written policy(ies) or procedures used by you to track purchases and sales of prescription drugs after January 1, 2011, and prior to the enactment of the DSCSA.
19. Documents that identify changes in written policies and procedures and the reasons for those changes.

IX. DOCUMENT PRESERVATION

20. Produce the final document/data retention or destruction policies, or sections thereof, if any, in effect during the time period from January 1, 2011 to December 31, 2019 and applicable to records of purchases and sales of LCDs and ICDs,

shipment documents accompanying purchases and sales of LCDs and ICDs, product testing documents accompanying purchases and sales of LCDs and ICDs, and LCD and ICD recall documents.

21. Documents that identify changes in retention or destruction policies and the reasons for those changes.

X. COMPLAINTS

22. Produce documents sufficient to show all complaints you received from anyone concerning the quality, purity or contamination of ICDs and LCDs during the time period from January 1, 2011 to December 31, 2019.

XI. INDEMNITY AGREEMENTS

23. Produce final written indemnification agreements applicable to any claims currently pending in MDL 2875 against Wholesaler Defendants.

XII. INSURANCE POLICIES

24. Produce all insurance policies which provide or may provide coverage for this action.

XIII. SALES AND PROFITS

25. Documents setting forth: (1) the sale price of all LCD and ICD pills, individually and in batches, lots, or other quantities utilized, (2) the profits to answering Defendant after deduction of any applicable expenses or costs, (3) any reimbursements, rebates, or subsidies provided to or from any person or entity in connection with the LCD and ICD pills.

Dated: May 22, 2023

/s/ Adam M. Slater

Adam M. Slater

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CERTIFICATE OF SERVICE

I certify that on the 22nd day of May 2023, I electronically transmitted the attached document to counsel of record in the above-captioned case.

/s/ Marlene J. Goldenberg
Marlene J. Goldenberg